**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| **IN RE: ARNTZEN, Charles T. et al.** | ) | |
| | ) | **APPEAL NO. _____** |
| **SERIAL NO: 10/733,135** | ) | |
| | ) | |
| **FOR: VACCINES EXPRESSED IN PLANTS** | ) | |
| | ) | **BRIEF ON APPEAL** |
| **FILED: December 11, 2003** | ) | |
| | ) | |
| **CONF NO: 8272** | ) | |
| | ) | |
| **GROUP ART UNIT: 1638** | ) | |
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| **ATTORNEY DOCKET: P00245US17** | ) | |

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Janaé E. Lehman Bell, Ph.D.

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## I. INTRODUCTION

This is an appeal of the non-final Rejection dated July 15, 2008 twice rejecting claims 1-10. The appealed claims 1-10 are set forth in the attached Claim Appendix.

## II. REAL PARTY OF INTEREST

The real party of interest for this application is ProdiGene, Incorporated, the Assignee of record for this application. The assignment has been recorded at Reel 008763 and Frame 0450 on December 11, 2003.

## III. RELATED APPEALS AND INTERFERENCES

None.

## IV. STATUS OF CLAIMS

Claims 1-14 were originally submitted December 11, 2003. In a Response to Office Action (Restriction Requirement) dated October 5, 2006, Appellant elected Group I (claims 1-10) and claims 11-14 were withdrawn. In an amendment dated June 20, 2007, Appellant amended claims 1, 4 and 8-10. In an Amendment accompanying a Request for Continued Examination filed October 31, 2007, Appellant amended claims 1, 6 and 8-9 and added claims 15-16. In an Amendment filed March 26, 2008 Appellant canceled claims 11-16. The final rejection mailed July 15, 2008 reinstated the rejections to claims 1-5 and 7-10 as obvious over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546) and to claim 6 as obvious over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264). The claims here appealed are claims 1-10.

## V. STATUS OF AMENDMENTS

A First Preliminary Amendment was filed August 21, 2006. A Restriction Election was filed October 24, 2006. An Amendment was filed June 20, 2007. A Request for Continued Examination (RCE) including an Amendment Accompanying a Request for Continued Examination was filed October 31, 2007. An Amendment was filed March 26, 2008. A Notice of Appeal is being filed concurrently with this Appeal Brief.

## VI. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claims 1, 8 and 10 relate to methods of producing an immunogenic composition. (see, e.g., specification as filed at page 8, line 33 to page 9, line 12, page 18, lines 16-19).

The method of claim 1 includes transforming a plant with a nucleic acid construct that expresses a recombinant mammalian viral immunogen in a plant. (see, e.g., specification as filed at page 12, lines 24 to 28, page 20, line 18 to page 22, line 11, Example IV, page 38, line 19 to page 47, line 10). The method further includes selecting those plants expressing the recombinant viral immunogen at a level such that upon oral administration of a composition having a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to the viral immunogen is elicited so that the animal is protected against viral challenge. (see, e.g., specification as filed at page 12, line 32 to page 13, line 2, page 20, line 18 to page 22, line 11, Example IV, page 38, line 19 to page 47, line 10). The method further includes producing from the plants the immunogenic composition. (see, e.g., specification as filed at page 13, lines 28 to 32, Example IV, at page 38, line 19 to page 47, line 10).

Independent claim 8 relates to a method of producing an immunogenic composition by introducing into a plant a nucleic acid construct which causes expression of a recombinant mammalian viral immunogen. (see, e.g., specification as filed at page 8, line 33 to page 9, line 12, page 12, lines 24 to 28). The immunogen is preferentially expressed in the edible tissues of the plant. (see, e.g., specification as filed at page 9, lines 18 to 19). The method further includes selecting those plants with expression in the tissue at a level such that upon oral administration of the tissue to an animal, an immunogenic response to the viral immunogen is observed to protect the animal against a viral challenge. (see, e.g.,

specification as filed at page 12, line 32 to page 13, line 2, page 20, lines 6 to 9, page 20, line 18 to page 22, line 11, Example IV, page 38, line 19 to page 47, line 10).

Independent claim 9 relates to a method of producing an immunogenic composition by obtaining a nucleic acid construct. (see, e.g., specification as filed at page 8, line 33 to page 9, line 12, page 12, lines 24 to 28). The construct includes a nucleotide sequence which encodes a recombinant mammalian viral immunogen and one or more of the following: a promoter sequence which preferentially targets expression to edible tissues of a plant, a 5' untranslated leader sequence, or an enhancer sequence. (see, e.g., specification as filed at page 8, line 33 to page 9, line 12, page 12, lines 24 to 28). The method further includes transforming a plant cell with the sequence so that expression of the recombinant viral immunogen is at a level such that upon oral administration of the plant an immunogenic response to the immunogen is observed to protect against a viral challenge. (see, e.g., specification as filed at page 13, line 33 to page 14, line 7, page 20, lines 6 to 9, page 20, line 18 to page 22, line 11, Example IV, page 38, line 19 to page 47, line 10). The method includes collecting plants with the expression level to form the immunogenic composition. (see, e.g., specification as filed at page 12, line 32 to page 13, line 2, Example IV, at page 38, line 19 to page 47, line 10).

## VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-5 and 7-10 are unpatentable over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546).

B. Whether claim 6 is unpatentable over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264).

## VIII. ARGUMENT

### A. The Examiner's Rejection of Claims 1-10 under 35 U.S.C. § 103(a) Has Been Improperly Maintained

1. The Law of Obviousness

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *see also In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). It is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). In so doing, the Examiner is expected to make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007) ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.")

> [T]he scope and content of the prior art ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

*Id.*, 127 S.Ct. at 1729-30, 82 USPQ2d at 1338 (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966)) (internal quotations omitted).

As the Supreme Court has recently articulated in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007), it can be "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. The Supreme Court only found obviousness

to be present after "convincing evidence" of obviousness was provided. *KSR,* 127 S.Ct. at 1746, 82 USPQ2d at 1400.

These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. *See Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444. Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444. *See also Piasecki*, 745 F.2d at 1472, 223 USPQ at 788. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444; *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788.

2. The Examiner's Conclusion of Obviousness is Based on an Incorrect Application of the Law to the Claimed Invention

a. The Examiner's Rejection of Claims 1-5 and 7-10 under 35 U.S.C. § 103(a) over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546) Has Been Improperly Maintained

1. Goodman et al. in view of Kapikian et al. individually or combined fail to teach or suggest "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge".

To make an obviousness determination, section 2143.03 of the MPEP requires the "consideration" of every claim feature. The Examiner has erred in this inquiry, as the Goodman reference and the Kapikian reference, alone or combined, fail to teach or suggest all the claim elements. *See also In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art).

Claim 1, from which claims 2-5 and 7 depend, recites "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal,

an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge". Independent claims 8 and 9 recite similar limitations.

The Examiner seems to urge that because the composition can comprise a recombinant viral immunogen that has been purified or concentrated, the claimed limits "at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge" is not considered as a further limitation of the claim. Office Action dated July 15, 2008 at page 3. Here, the Examiner has rewritten the claims to encompass any expression level of an immunogen where an immune response cannot be achieved, when Appellant's invention is not so broadly claimed and disregards the differences in the claim limits. Indeed, the Examiner's interpretation disregards the teachings of *KSR Int'l* requiring an analysis of the *Graham* factors, specifically of ascertaining the differences between the prior art and the claims at issue.

The Examiner has further failed to meet the requirements articulated in *KSR Int'l* in determining the scope and content of the prior art. The Examiner cites Goodman et al. for teaching the expression of an immunogenic protein in a plant. (emphasis added). Office Action dated Jan. 18, 2007, at page 9. The Examiner seems to be taking a very broad view of the disclosure in Goodman et al., broader than the actual disclosure or that supported in the decision by the Board of Patent Appeals and Interferences (BPAI)) (*Ex parte* Roy Curtiss III and Guy A. Cardineau, Appeal No. 93-4341, Heard January 11, 1996), hereinafter referred to as *Ex parte* Curtiss.

Goodman et al. describe using a transgenic plant to expresses murine interferon gamma. Goodman et al., '282, Col. 5- Col.10. These proteins are then administered to animals for their inherent biological functions, not their immunogenic properties. Appellant's view about the Goodman reference is bolstered by a decision in *Ex parte* Curtiss. The Board explicitly stated that the Goodman reference does not teach a transgenic plant that expresses an antigenic protein and induces an immune response in animals. The Board held:

> Where the product can have a physiological effect on ingestion, Goodman discloses, it may be sufficient that the product be retained within the plant. This will be true where the plant part is edible. See Goodman, paragraph

> bridging pages 9 and 10. However, Goodman does not disclose or suggest retaining in the plant a protein which has no effect on ingestion. Like all of the references discussed above, **Goodman does not disclose or suggest a transgenic plant which (a) expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of *Streptococcus mutans* or *Escherichia coli*, and (b) induces a secretory immune response to *Streptococcus mutans* or *Escherichia coli* in a human or other animal, said immune response elicited by the antigen expressed in said plant.** (*emphasis added*)

*Ex parte* Curtiss, at pages 11-12. The Examiner argues that when Appellant points to this Board decision, Appellant is citing a nonprecendential ruling and the fact pattern in that case is different than the fact pattern of the instant case, and that the rejections are not identical. Here, however, Appellant is not stating that the fact patterns or rejections are identical to the Board decision or that the decision is precedential, but is providing analysis by pointing out the differences in the claim limits of the Goodman reference and the claimed invention. Goodman et al. do not teach expressing an immunogen, much less expressing an immunogen in a plant at such a level that when a composition comprising the immunogen is consumed by an animal the composition elicits an immune response in the animal. Kapikian et al. fail to supply the teachings that are lacking in Goodman et al. Appellant submits that the Kapikian reference describes the state of the art concerning possible human rotavirus vaccines, specifically vaccines of attenuated, whole rotaviruses from animals, not plants and not directed to individual recombinant, viral immunogenic proteins. Clearly, the Examiner has failed to properly determine the scope and content of the prior art and ascertain the differences between the prior art and the claims at issue as required under *KSR*. Therefore, the Examiner has not met the burden of making a *prima facie* case of obviousness and the claimed invention is not obvious. Therefore, the section 103(a) rejection of claims 1-5 and 7-10 should be reversed.

2. <u>The Examiner has failed to provide a reasonable expectation of success and convincing evidence or line of reasoning for combining Goodman et al. with Kapikian et al.</u>

To make an obviousness determination, section 2143.02 of the MPEP provides that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231

USPQ 375 (Fed. Cir. 1986). Appellant respectfully submits that in the instant case there is no reasonable expectation of success to produce an immunogenic composition by transforming a plant with a nucleic acid construct that expresses a recombinant mammalian viral immunogen in a plant and therefore Goodman et al. and Kapikian et al. should not be combined or modified. Accordingly, the Examiner has erred in the application of the law and thus, the Examiner should be reversed.

The Examiner states that one would expect success in combining the teachings "[g]iven the success of producing recombinant therapeutic proteins in plants taught by Goodman et al. and the success of utilizing recombinant proteins for vaccines as taught by Kapikian et al." Office Action, July 15, 2008, at pages 5-6. The Examiner states that "Given the recognition of those of ordinary skill in the art of the value of expressing an immunogenic protein in a plant as taught by Goodman et al., it would have been obvious to one of ordinary skill in the art to use the method of Goodman et al. and to modify said method using the sequences encoding the immunogens taught by Kapikian et al." Office Action, July 15, 2008, at page 5.

Appellant disagrees with the Examiner's characterization of the references and her conclusions. As discussed above, Goodman et al. contemplate the use of a transgenic plant to produce a protein that is not immunogenic. Further, due to viral tropism, a mammalian viral immunogen would normally only be expected to express in a mammalian cell since the virus relies on mammalian host cell factors for expression. Here, the mammalian viral immunogen nucleotide sequence relies solely on plant machinery for proper expression and folding. There is no reasonable expectation of success that the mammalian viral immunogenic protein would (a) even be expressed and (b) would be correctly processed so that it would retain immunogenic properties. Thus, Goodman et al. and Kapikian et al. do not provide one of ordinary skill in the art a reasonable expectation of success for the claimed methods. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP §§ 2142 and 2143.02.

Assuming *arguendo* that a reasonable expectation of success exists, as recognized in *KSR*, under the teaching, suggestion, motivation test, "it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does." *KSR*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007).

Appellant respectfully submits that the claimed invention is not obvious as the Examiner failed to identify a reason to combine the references in the manner claimed.

The Examiner cites Kapikian et al. for the proposition of "the success of utilizing recombinant proteins for vaccines as taught by Kapikian et al." Office Action, Jan. 18, 2007, page 10. Appellant submits that when the Kapikian reference is read as a whole, the reference teaches the state of the art concerning possible human rotavirus vaccines, specifically vaccines of attenuated, whole rotaviruses from animals, not plants and not directed to individual recombinant, viral immunogenic proteins. Thus, one of ordinary skill in the art would not have made the combination of Goodman et al. and Kapikian et al. to arrive at the present invention. One skilled in the art at the time of the invention would have seen no relevance of the Goodman patent to the Kapikian article and would not have modified methods based on these references.

In the instant case, there is no apparent reason for one skilled in the art to use the method of Goodman et al. and to modify the method using the sequences of Kapikian et al. in the absence of Appellant's disclosure. Appellant notes that this application claims a benefit of priority to August 26, 1991. It is critical when making an obviousness determination to cast one skilled in the art's mind back to the time of the invention, here, back to 1991. Indeed, *KSR* warns that factfinders "should be aware ... of the distortion caused by hindsight bias and must be cautious of arguments reliant on *ex post* reasoning" and use of hindsight (as done here) is impermissible. *KSR*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007).

For at least these reasons, one of ordinary skill in the art at the time of invention would not have had a reasonable expectation in advance that a viral immunogen would be able to be expressed and folded property in a plant such the immunogen would possess immunogenic properties when administered to an animal, much less have had any motivation to combine the prior art elements in the manner claimed. Accordingly, the Examiner has failed to provide convincing evidence of obviousness as required under *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1746, 82 USPQ2d 1385, 1396 (2007). As the Supreme Court has recently articulated in *KSR*, it can be "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR*, 127 S.Ct. at 1747, 82 USPQ2d at 1396.

The Supreme Court only found obviousness to be present after "convincing evidence" of obviousness was provided. *Id.* at 1400. Therefore, the Examiner has provided no such convincing evidence or line of reasoning, and therefore the claimed invention is patentable and not obvious. The rejection of claims 1-5 and 7-10 should be reversed.

b. The Examiner's Rejection of Claim 6 over 35 U.S.C. § 103(a) over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264) Has Been Improperly Maintained

To make an obviousness determination, section 2143.03 of the MPEP requires the "consideration" of every claim feature. The Examiner has erred in this inquiry, as the Goodman reference, in view of Kapikian et al., and further in view of Kay et al., and further in view of Gallie et al., alone or combined, fail to teach or suggest all the claim elements. *See also In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art).

Claim 6 recites, "The method of claim 1 further comprising the step of: introducing into said plant a nucleotide sequence designed for expression of said immunogen comprising one of more of the following features: a promoter sequence which preferentially targets expression to edible tissues of a plant; a 5' untranslated leader sequence; and an enhancer sequence."

Appellant does not rely upon the features of claim 6 for separate patentability apart from the parent claim from which it depends, claim 1. Claim 1 recites in part, "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration ... an immunogenic response to said viral immunogen is elicited".

In this rejection, the Examiner cites in addition to the Goodman and Kapikian references, Kay et al. and Gallie et al. and essentially makes the same argument that "it would have been obvious to one of ordinary skill in the art to use the method of Goodman et al. and to modify said method by using the enhancer taught by Kay et al. and the 5'

untranslated leader sequence taught by Gallie et al. and by expressing immunogens taught by Kapikian et al." Office Action, July 15, 2008, at page 9.

As discussed previously, the Goodman reference does not teach a method of producing a recombinant viral immunogen in a plant as found in the Appellant's claim 1. Kapikian et al., Kay et al. and Gallie et al. fail to supply the teachings that are lacking in Goodman et al. Clearly, the combination of references fails to teach or suggest the limitations of claim 1 and thus cannot render claim 1 obvious. The Examiner has failed to make out a *prima facie* case of obviousness as neither the Goodman, Kapikian, Kay nor Gallie references, alone or combined, teach each and every element of claim 1 and therefore cannot render the claim obvious. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Therefore, the Examiner has failed to properly determine the scope and content of the prior art as required under *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007), (noting that the *Graham* factors continue to define the inquiry that controls). Thus, the Examiner has failed to establish a *prima facie* case of obviousness and the claimed invention is not obvious.

Further, as discussed previously, the prior art references, alone or combined, fail to provide a reasonable expectation of success for producing an immunogenic composition. M.P.E.P. § 2143.02. Accordingly, the Examiner has failed to provide convincing evidence of obviousness as required under *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1746, 82 USPQ2d 1385, 1400 (2007). Therefore, the claimed invention is not obvious. In light of the above, claim 1 is not obvious. Claim 6 dependent on claim 1 is likewise not obvious for the reasons argued above, plus the elements in the claim. Accordingly, the rejection of claim 6 should be reversed.

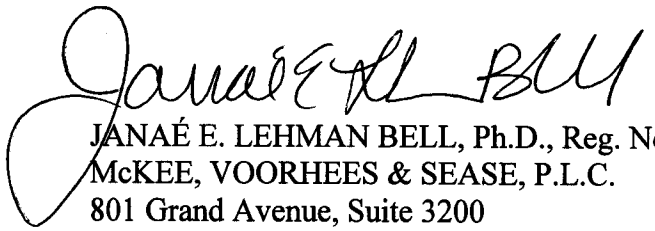
## IX. CONCLUSION

In sum, the Examiner has not satisfied the legal standards for obviousness as set forth in case law and the MPEP. Appellant therefore respectfully requests that the Examiner's rejections under 35 U.S.C. § 103(a) be reversed and the claims allowed.

Being filed with this Appeal Brief is the Notice of Appeal and Petition for One-month Extension of Time along with the fees shown on each.

Please charge Deposit Account No. 26-0084 the amount of $270.00 for this Appeal Brief. No other fees or extensions of time are believed to be due in connection with this appeal; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



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## X. CLAIMS APPENDIX

1. A method of producing an immunogenic composition comprising

transforming a plant with a nucleic acid construct that expresses a recombinant mammalian viral immunogen in a plant,

selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge, and

producing from said plants said immunogenic composition.

2. The method of claim 1, wherein said immunogen is capable of generating an immunogenic response when the immunogen interacts with a mucosal membrane.

3. The method of claim 1, wherein said immunogen is from a transmissible gastroenteritis virus.

4. The method of claim 1 further comprising:

selecting edible plant tissue expressing said immunogen at a level such that a composition comprising said immunogen induces an immunogenic response upon administration to an animal, wherein said level of immunogen correlates with expression levels of said immunogen in said tissue.

5. The method of claim 1, wherein said plant is a dicotyledonous plant.

6. The method of claim 1 further comprising the step of:

introducing into said plant a nucleotide sequence designed for expression of said immunogen comprising one of more of the following features:

a promoter sequence which preferentially targets expression to edible tissues of a plant;

a 5' untranslated leader sequence; and

an enhancer sequence.

7. The method of claim 1 wherein said plant is a monocot plant.

8. A method of producing an immunogenic composition comprising:
introducing into a plant a nucleic acid construct which causes expression of a recombinant mammalian viral immunogen preferentially in the edible tissues of said plant, and
selecting those plants with expression in said tissue at a level such that upon oral administration of said tissue to an animal, an immunogenic response to said viral immunogen is observed to protect said animal against a viral challenge, thereby forming said immunogenic composition.

9. A method of producing an immunogenic composition comprising obtaining a nucleic acid construct, said construct comprising:
a nucleotide sequence which encodes a recombinant mammalian viral immunogen and one or more of the following:
a promoter sequence which preferentially targets expression to edible tissues of a plant;
a 5' untranslated leader sequence;
an enhancer sequence;
transforming a plant cell with said sequence so that expression of the recombinant viral immunogen is at a level such that upon oral administration of the plant an immunogenic response to said immunogen is observed to protect against a viral challenge, and
collecting plants with said expression level to form said immunogenic composition.

10. The method of claim 1, wherein said plant is a plant edible by an animal.

## XI. EVIDENCE APPENDIX

Only evidence of record has been relied upon in this appeal.

## XII. RELATED PROCEEDINGS APPENDIX

There are no related proceedings in the present appeal of U.S. Application No. 10/733,135.